industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term *polychlorinated biphenyls (PCB's)* is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled ''Analytical Methodology for Polychlorinated Biphenyls, February 1973'' for determining compliance with the tolerances established in this section is available from the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 510—NEW ANIMAL DRUGS

Subpart A—General Provisions

Subpart B—Specific Administrative Rulings and Decisions

Subpart C [Reserved]

Subpart D—Records and Reports

Subpart E—Requirements for Specific New Animal Drugs

Subpart F [Reserved]

Subpart G—Sponsors of Approved Applications

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 321–392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) *Person* means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research* and *laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) *Sponsor* means the person requesting designation for a minor-use or minor-species drug as defined in part 516 of this chapter, who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the

person responsible for an investigation of a new animal drug. In this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs. Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts, the sponsor is responsible for compliance with applicable provisions of the act and regulations.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989; 64 FR 69190, Dec. 10, 1999; 72 FR 41017, July 26, 2007]

§ 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Holds a license issued under § 515.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 515.10 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

[40 FR 13807, Mar. 27, 1975, as amended at 64 FR 63203, Nov. 19, 1999]

§ 510.95 [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 526 of this chapter provides for new animal drugs intended for intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(c)(ii) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the following statement: ''Warning: Milk that has been taken from animals during treatment and for ____ hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry violative residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

[40 FR 13807, Mar. 27, 1975, as amended at 63 FR 32980, June 17, 1998; 64 FR 51241, Sept. 22, 1999]

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement ''Warning: Not for use in animals producing milk, since this use will result in contamination of the milk'' or the statement ''Warning: Milk that has been taken from animals during treatment and for ___hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt the drug from bearing either of the above warning statements.

[63 FR 32980, June 17, 1998]

§ 510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, § 510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the date of publication of § 510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Pub. L. 85–929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those

products for which there are inadequate residue data, actions will be initiated to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations, including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 64 FR 403, Jan. 5, 1999]

§ 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Nonmedical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been accumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations the data shall be submitted within 60 days of such publication. Data demonstrating the absence in milk of residues of intramammary infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 46 FR 8460, Jan. 27, 1981; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

Subpart C [Reserved]

Subpart D—Records and Reports

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) or index listing(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application or request for determination of eligibility for indexing.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or in support of the index listing or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or in support of the index listing or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 72 FR 69121, Dec. 6, 2007]

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved or index listed labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

[64 FR 63203, Nov. 19, 1999, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart E—Requirements for Specific New Animal Drugs

§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed?* For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements (''lick tank'' supplements) containing one or more new animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations in part 225 of this chapter for medicated feeds.

(b) *What is required for new animal drugs intended for use in free-choice feed*? Any new animal drug intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)) or listed in the index under section 572 of the act (21 U.S.C. 360ccc–1). Such approvals under section 512 of the act must be:

(1) An original new animal drug application (NADA),

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(c) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in free-choice feed*? An approval under section 512 of the act for a Type A medicated article intended for use in free-choice feed must contain the following information:

(1) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(2) Data, or reference to data in an MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted?* The data must be submitted as follows:

(1) Directly in the NADA, by a sponsor; and/or

(2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed?* The approval of a new animal drug intended for use in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication, or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-*

choice medicated feed? An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All free-choice medicated feeds that contain a Category II drug, and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

[69 FR 30197, May 27, 2004, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart F [Reserved]

Subpart G—Sponsors of Approved Applications

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527	057699
AB Science, 3 Avenue George V, 75008 Paris, France	052913
Abbott Laboratories, North Chicago, IL 60064	000074
ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115	012286
Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	024174
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712	064146
Alpharma, LLC, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017	046573
Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB	062408
American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140	065531
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052	051212
Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218	076175
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756	067188
Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974	010019
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	000859
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	062250
Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601	064847
Bioniche Teoranta, Inverin, County Galway, Ireland	063286
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435	051359
BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	032761
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002	000010
Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767	068330
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105	021091
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067	055462
Cooperative Research Farms, Box 69, Charlotteville, NY 12036	051267
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	046987
Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom	043264
ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131	066916
Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254	061088
Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	000986
Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317	060951
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928	017135
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	058829
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017	000856
Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017	053501
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463
G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201	010515
G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077	000014
Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302	050972
GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702	042976
Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661	012164
Happy Jack, Inc., Snow Hill, NC 28580	023851
Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525	063604
Hess & Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511	050749
Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria	016592
I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	050639
IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409	065274
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
International Nutrition, Inc., 7706 'I' Plaza, Omaha, NE 68127	043733
Intervet, Inc., 556 Morris Ave., Summit, NJ 07901	000061
Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214	021641
J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704	039741
Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium	012578
K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214	038782
Land O' Lakes Purina Feed LLC, 100 Danforth Dr., Gray Summit, MO 63039	066071
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	061690
Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967	010797
Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525	058711
Marsam Pharmaceuticals, LLC, Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034	000209
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861	054925
Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258	099207
Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	050604
Micro Beef Technologies LTD, P.O. Box 9262, Amarillo, TX 79105	047126
Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214	059620
Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146	015914
Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120	049968
Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	055529
Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	058198
Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9	043806
NutriBasics Co., North Highway 71, P.O. Box 1014, WIllmar, MN 56201	053740
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA 02141	063075
OXIS International, Inc., 6040 N. Cutter Circle, Suite 317, Portland, OR 97217–3935	024991
Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904	046129
Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia	068504
Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402	028459
Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	055246
Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144	048164
Pfizer, Inc., 235 East 42d St., New York, NY 10017	000069
Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970	050057
Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017	000009
Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069	042552
Pharmaq AS, Skogmo Industriomrade, N–7863 Overhalla, Norway.	015331
Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660	066104
Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017	066794
Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, India	065085
Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil	060728
Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338	017790
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812	017800
Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	026637
Quali-Tech Products, Inc., 318 Lake Hazeltine Drive, Chaska, MN 55318	016968
Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349	076475
R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518	011014
Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	068287
Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	067949
RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474	067292
RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620	058670
Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201	011749
Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250	063112
Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406	049685
Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	058005

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087	035955
Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151	017153
Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752	037990
Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062	027053
Synerx Pharma, LLC, 100 N. State St., Newtown, PA 18940–2048	068882
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532	051672
Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503	059130
Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218	000842
Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503	052923
Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204	051330
UDL Laboratories, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478	051079
United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711	058639
Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.	055882
Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354	033008
Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5	059320
Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	051311
Walco International, Inc., 15 West Putnam, Porterville, CA 93257	049185
Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.	000402
Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048	034936
Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363	035098
Wellmark International, 1501 East Woodfield Rd., suite 200 West, Schaumburg, IL 60173	011536
West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153	033392
West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724	000143
Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248	050378
Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524	053923
Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101	000008

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
000008	Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101.
000009	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017.
000010	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.
000014	G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077.
000061	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.
000069	Pfizer, Inc., 235 East 42d St., New York, NY 10017.
000074	Abbott Laboratories, North Chicago, IL 60064.
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544
000143	West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724.
000209	Marsam Pharmaceuticals, LLC, Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.
000402	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
000842	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.
000856	Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017
000859	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.
000986	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.
010019	Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974.
010515	G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201.
010797	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.
011014	R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518.
011536	Wellmark International, 1501 East Woodfield Rd., suite 200 West, Schaumburg, IL 60173.
012164	Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661.
012286	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115.
012578	Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium
015331	Pharmaq AS, Skogmo Industriomrade, N–7863 Overhalla, Norway.
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
015914	Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146
016592	Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria.
016968	Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.
017135	Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928.
017153	Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151.
017762	Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112.
017790	Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338.
017800	Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812.
021091	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.
021641	Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214.
023851	Happy Jack, Inc., Snow Hill, NC 28580.
024174	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
024991	OXIS International, Inc., 6040 N. Cutter Circle, Suite 317 Portland, OR 97217–3935.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747.
026637	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101.
027053	Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062.
028459	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.
032761	BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704.
033008	Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354.
033392	West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153.
034936	Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048.
035098	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363.
035955	Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087.
037990	Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.
038782	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
039741	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.
042552	Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069.
042976	GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702.
043264	Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom.
043733	International Nutrition, Inc., 7706 'I' Plaza, Omaha, NE 68127.
043806	Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9.
046129	Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904.
046573	Alpharma, LLC, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017
046987	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
047126	Micro Beef Technologies LTD, P.O. Box 9262, Amarillo, TX 79105.
048164	Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144.
049185	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.
049968	Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120.
050057	Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970.
050378	Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248.
050604	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.
050639	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137.
050749	Hess & Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.
050972	Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302.
051079	UDL Laboratories, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478.
051212	Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052.
051267	Cooperative Research Farms, Box 69, Charlotteville, NY 12036.
051311	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137.
051330	Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204
051359	Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44141.
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland.
052913	AB Science, 3 Avenue George V, 75008 Paris, France.
052923	Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503
053501	Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017
053923	Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524.
054925	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.
055246	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.
055462	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067.
055529	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.
055882	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503.
057699	A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527.
058005	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.
058198	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408.
058639	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.
058670	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.
058711	Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525.
058829	First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123.
059130	Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503.
059320	Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5.
059620	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.Blvd., St. Louis, MO 63167.
060728	Planalquimica Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Alto, Brazil.
060865	Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801.
060951	Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317.
061088	Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254.
061623	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.
061651	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.
061690	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.
062250	Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777.
062408	Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
062794	Mylan Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478
063075	OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA 02141
063112	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.
063286	Bioniche Teoranta, Inverin, County Galway, Ireland
063604	Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.
064146	Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712.
064847	Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601.
065085	Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, India.
065274	IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409.
065531	American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140.
066071	Land O' Lakes Purina Feed LLC, 100 Danforth Dr., Gray Summit, MO 63039.
066104	Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660.
066794	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017.
066916	ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131
067188	B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.
067292	RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474.
067949	Ridley U.S. Holdings, Inc., 424 N. Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500.
068287	Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.
068330	Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767
068504	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia
068882	Synerx Pharma, LLC, 100 N. State St., Newtown, PA 18940–2048
076175	Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218.
076475	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349
099207	Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258.

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

EDITORIAL NOTE: At 72 FR 36595, July 5, 2007, §510.600, in the table in paragraph (c)(2), was amended by removing the entry for ''062749''; however, the amendment could not be incorporated because the entry does not exist.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

§511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.